DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: ALDARA™
Docket No. 97E-0269

#16

SEP 29 1998

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 5,238,944, filed by Riker Laboratories, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for ALDARA™, the human drug product claimed by the patent.

The total length of the regulatory review period for ALDARA™ is 3,471 days. Of this time, 3,254 days occurred during the testing phase and 217 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: August 30, 1987.

   The applicant claims September 1, 1987, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 30, 1987, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: July 26, 1996.

   The applicant claims July 25, 1996, as the date the New Drug Application (NDA) for ALDARA™ (NDA 20-723) was initially submitted. However, FDA records indicate that NDA 20-723 was submitted on July 26, 1996

3. The date the application was approved: February 27, 1997.

   FDA has verified the applicant's claim that NDA 20-723 was approved on February 27, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Ted K. Ringsred
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